





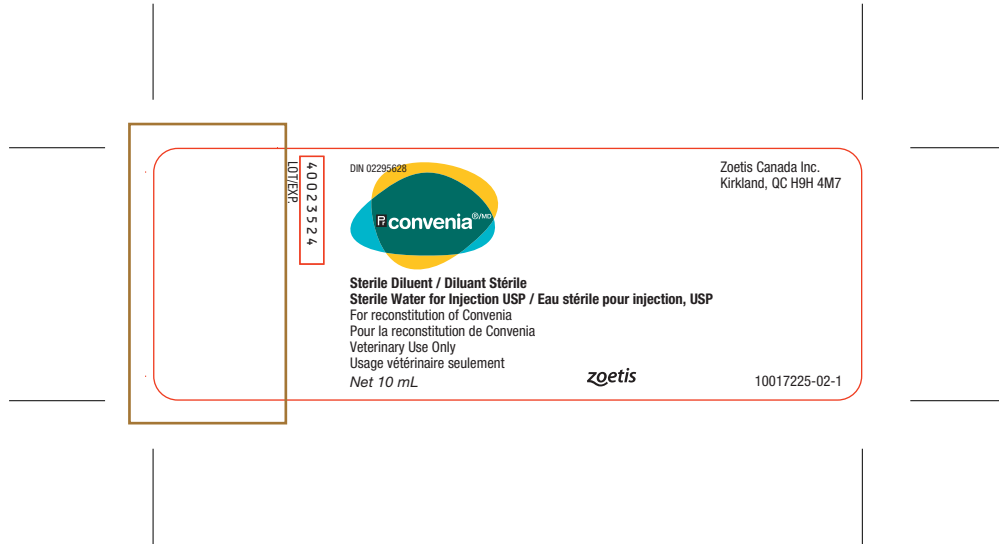

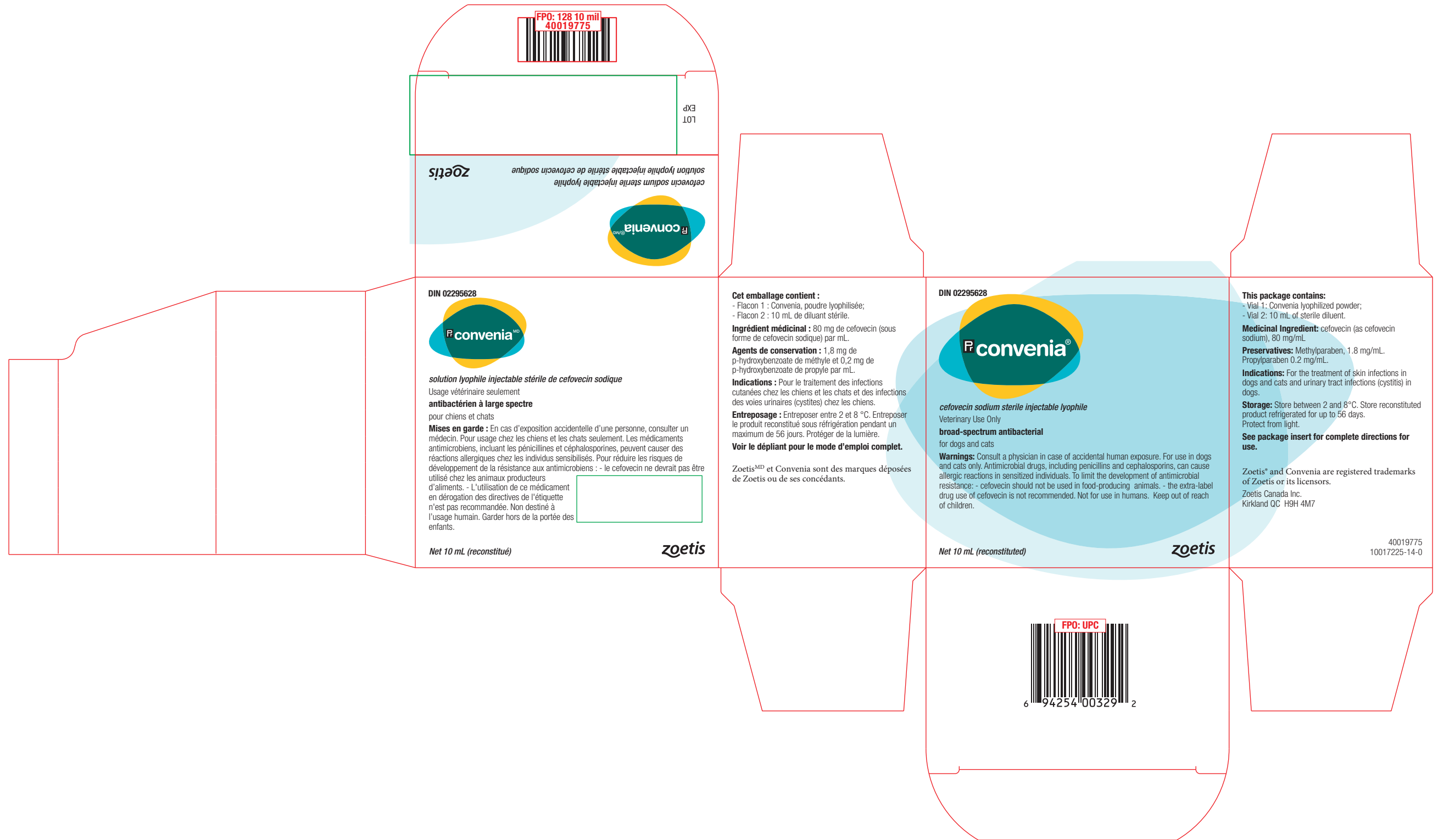


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	3.687" x 1.312"			Z14-800728			10017225		Z63 Label	
Additional Info:		Colors:  Black  PMS 123  PMS 3292  PMS 3125  Dieline  No Varnish						<input type="checkbox"/> EDITOR'S COPY		
									GS: DATE:	
GS	W. Floyd	Rev	GA	PR	CHANGES	GS / ART REV (LCA)	CHANGES	GS / ART REV (FA)	CHANGES	
GA	J. Disch	1	JD		OK		OK		OK	



zoetis Artwork Center: US			AWC Representative K. Minard 	Plant Name / Code Kalamazoo/US60
QN / Project No. 200005597	FG Material No. 10017225	New Material No. 40023524	Description LABEL DILUENT CONVENIA 10ML	
DIR No. / Version No. 505734 /01	Specification / DWG Z14-800570	Old Material No. 40019778	Countries CA	
Dimensions 3.687" x 1.312"		Colors		
Additional Info. Semi-Finished Goods 40016725		BLACK	PMS 123	PMS 3292
		PMS 3125	DieLine	No Varnish
		Version No. v1	Date 40023524.pdf 1 8/29/18 2:40 PM	



Zoetis, March 19, 2021

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Additional Info: Artwork is GTIN Ready		Colors: Black PMS 123 PMS 3292 PMS 3125 Dieline No Varnish				<input type="checkbox"/> EDITOR'S COPY GS: DATE:
GS	W. Floyd	Rev	GA	PR	CHANGES	GS / ART REV (LCA)
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DIN 02295628



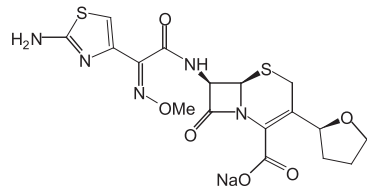
cefovecin sodium sterile injectable lyophile

Veterinary Use Only

For Subcutaneous Use in Dogs and Cats Only

DESCRIPTION: Cefovecin is a semi-synthetic broad-spectrum antibacterial agent from the cephalosporin class of chemotherapeutic agents.

Figure 1: Chemical structure of cefovecin sodium.



Each mL of CONVENIA® Injectable Lyophile reconstituted lyophile contains cefovecin sodium equivalent to 80.0 mg cefovecin, methylparaben 1.8 mg and propylparaben 0.2 mg as preservatives.

INDICATIONS: CONVENIA Injectable Lyophile is indicated for the treatment of bacterial infections in dogs and cats with the following conditions:

DOGS SKIN: Skin infections including bacterial folliculitis, wounds, and abscesses caused by susceptible strains of Staphylococcus intermedius, Streptococcus canis (Group G, beta-hemolytic), and Escherichia coli.

CATS SKIN: Skin infections including abscesses and wounds caused by susceptible strains of Pasteurella multocida, Prevotella bivia, Bacteroides fragilis, and Staphylococcus intermedius.

EFFICACY CONFIRMATION: In controlled, double blind, 1:1 randomized field studies conducted in the United States, the efficacy of cefovecin was compared to cefadroxil.

Table with 4 columns: Type of Infection, Dogs (Cefovecin, Cefadroxil), Cats (Cefovecin, Cefadroxil)

There were no serious adverse events reported during clinical field studies with either cefovecin or cefadroxil.

DOSAGE AND ADMINISTRATION: To deliver the appropriate dose, reconstitute CONVENIA Injectable Lyophile with 10 mL Sterile Water for Injection, USP.

CONVENIA Injectable Lyophile is to be administered as a single subcutaneous injection at a dosage of 8 mg/kg or 0.1 mL/kg.

28 days. Factors to be considered in the determination of an additional dose are the nature and severity of the infection, the susceptibility of the pathogen, and the immune status of the animal.

CLINICAL PHARMACOLOGY: Cefovecin is rapidly and completely absorbed following subcutaneous administration.

Pharmacokinetic parameters following subcutaneous dosing at 8 mg/kg in the dog and cat are summarized in Figures 2a, and 2b, and in Table 1.

Figure 2a: Mean Plasma and Urine Concentrations following a Single 8 mg/kg Subcutaneous Dosage of CONVENIA Injectable Lyophile in Dogs.

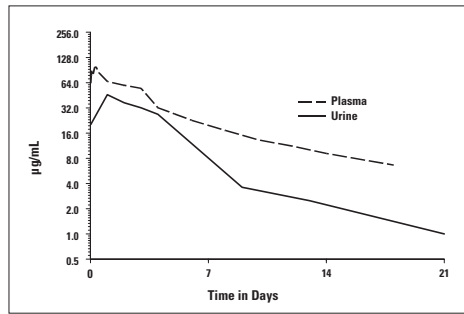


Figure 2b: Mean Plasma and Urine Concentrations following a Single 8 mg/kg Subcutaneous Dosage of CONVENIA Injectable Lyophile in Cats.

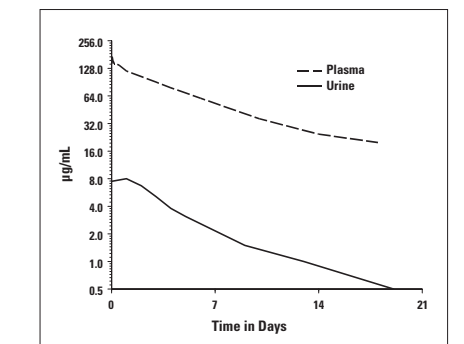


Table 1: Pharmacokinetic Parameters of a Single 8 mg/kg Subcutaneous Dosage of CONVENIA Injectable Lyophile in Dogs and Cats

Table with 3 columns: Parameter, Dogs, Cats

MICROBIOLOGY: CONVENIA Injectable Lyophile is a broad-spectrum cephalosporin with activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria including beta-lactamase producing strains.

Table 2: MIC Values of CONVENIA Injectable Lyophile Against Bacterial Pathogens Isolated From Skin and Urinary Tract Infections in Dogs Enrolled in Clinical Studies Conducted in the U.S. From 2001 to 2003.

Table with 5 columns: Organism, Number of Isolates, Range, MIC50, MIC90

Table 3: MIC Values of CONVENIA Injectable Lyophile Against Bacterial Pathogens Isolated From Dogs (2000 to 2001).*

Table with 5 columns: Organism, Number of Isolates, Range, MIC50, MIC90

*Correlation between in vitro susceptibility data and clinical response has not been determined.

Table 4: MIC Values of CONVENIA Injectable Lyophile Against Bacterial Pathogens Isolated From Skin Infections in Cats Enrolled in Clinical Studies Conducted in the U.S. From 2001 to 2003.

Table with 5 columns: Organism, Number of Isolates, Range, MIC50, MIC90

Table 5: MIC Values of CONVENIA Injectable Lyophile Against Bacterial Pathogens Isolated From Cats (2000 to 2001).*

Table with 5 columns: Organism, Number of Isolates, Range, MIC50, MIC90

*Correlation between in vitro susceptibility data and clinical response has not been determined.

Susceptibility Testing

The interpretive criteria proposed in this section were determined in accordance with the National Committee for Clinical Laboratory Standards (NCCLS).

Dilution Techniques: Quantitative methods are used to determine antimicrobial minimal inhibitory concentrations (MICs).

Diffusion Techniques: Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds.

Cefovecin MIC values and zone diameters should be interpreted according to the following proposed breakpoint criteria:

Table with 3 columns: MIC (µg/mL), Zone diameter (mm), Interpretation

A report of "Susceptible" indicates that the pathogen is likely to be inhibited by generally achievable drug concentrations.

Standardized susceptibility test procedures require the use of laboratory control organisms to control the technical aspects of the laboratory procedures.

Table with 3 columns: Control Strain, Broth Microdilution, Agar Dilution

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures.

Table with 2 columns: Control Strain, Zone diameter (mm)

CONTRAINDICATIONS: CONVENIA should not be administered to dogs or cats with a known allergy to cephalosporins.

CAUTIONS: The safe use of CONVENIA Injectable Lyophile in animals less than 4 months of age, pregnant dogs, dogs used for breeding purposes or in lactating dogs has not been established.

Positive direct Coombs' test results and false positive reactions for glucose in the urine have been reported during treatment with some cephalosporin antibacterials.

WARNINGS: Keep out of reach of children. Not for use in humans. Consult a physician in case of accidental human exposure.

SAFETY: Laboratory and clinical field studies have demonstrated that CONVENIA Injectable Lyophile is well tolerated in dogs and cats after subcutaneous administration.

DOGS: Sixty-three different pure breeds and 25 different mixed breeds were represented in the 393 dogs enrolled in clinical field studies.

In a margin of safety study, CONVENIA Injectable Lyophile was administered subcutaneously to healthy 4-month old beagle dogs at 1.5, 4.5, and 7.5 times the label dosage (12, 36, or 60 mg/kg).

In a separate 30-day drug tolerance study, healthy 7-month old beagle dogs were administered a single subcutaneous dose at 22.5 times the label dosage (180 mg/kg).

CONVENIA Injectable Lyophile is to be administered as a single subcutaneous injection at a dosage of 8 mg/kg or 0.1 mL/kg.

CONVENIA Injectable Lyophile is to be administered as a single subcutaneous injection at a dosage of 8 mg/kg or 0.1 mL/kg.

In a margin of safety study, CONVENIA Injectable Lyophile was administered subcutaneously to healthy 4-month old domestic shorthair cats at 1.5, 4.5, and 7.5 times the label dosage (12, 36, or 60 mg/kg).

In a separate 30-day drug tolerance study, healthy 7-month old domestic shorthair cats were administered a single subcutaneous dose at 22.5 times the label dosage (180 mg/kg).

ADVERSE REACTIONS: Although all adverse reactions are not reported, the following information is based on voluntary post-approval drug experience reporting.

CATS: - Systemic disorders: anorexia, lethargy, death, lack of efficacy, weight loss, fever

There were no serious adverse events reported during clinical field studies with CONVENIA. Injectable Lyophile.

Table 6: Number (Percentage) of Animals with Abnormal Health Observations Reported During Clinical Field Studies with CONVENIA Injectable Lyophile.

Table with 5 columns: Abnormal Observation, Dogs (Cefovecin, Cefadroxil), Cats (Cefovecin, Cefadroxil)

STORAGE: Store un-reconstituted product in the original carton refrigerated at 2 to 8°C.

Store reconstituted product in the original carton refrigerated for up to 56 days.

PRESENTATION: CONVENIA Injectable Lyophile package contains: vial 1, cefovecin sodium as a lyophilized cake; and vial 2, 10 mL of sterile diluent.

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Zoetis Canada Inc. Kirkland QC H9H 4M7



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Project information table with columns: Project No., Artwork DIR No., Component Material No., Description, Country, Dimensions, Drawing No., FG Material No., DIR Type/Description

Zoetis, March 19, 2021



French Labelling Attestation

I attest that the attached labelling for:

CONVENIA

cefovecin sodium sterile injectable lyophile

- a) has been translated into French by a professional translator; and
- b) that the French version is an accurate translation of the English labels included herein.

A handwritten signature in blue ink, appearing to read "Vincent ROUX".

Vincent ROUX, DVM
Senior Manager Regulatory Affairs
Zoetis Canada Inc.

March 19, 2021

Date